part if the application does not consistently and accurately import, store, and verify the digital signature.

(3) If other information required under this chapter cannot be consistently and accurately imported, stored, and displayed, the third-party auditor or certification organization must indicate that the application has failed to meet the requirements for the specific information and should not be used to process electronic prescriptions that require the additional information.

§ 1311.302 Additional application provider requirements.

(a) If an application provider identifies or is made aware of any issue with its application that make the application non-compliant with the requirements of this part, the application provider must notify practitioners or pharmacies that use the application as soon as feasible, but no later than five business days after discovery, that the application should not be used to issue or process electronic controlled substance prescriptions.

(b) When providing practitioners or pharmacies with updates to any issue that makes the application non-compliant with the requirements of this part, the application provider must indicate that the updates must be installed before the practitioner or pharmacy may use the application to issue or process electronic controlled substance prescriptions.

§ 1311.305 Recordkeeping.

(a) If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.

(b) Records required by this subpart must be maintained electronically for two years from the date of their creation or receipt. This record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other Federal or State law or regulation, applicable to practitioners, pharmacists, or pharmacies.

(c) Records regarding controlled substances prescriptions must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.

(d) Records required by this part must be made available to the Administration upon request.

(e) If an application service provider ceases to provide an electronic prescription application or an electronic pharmacy application or if a registrant ceases to use an application service provider, the application service provider must transfer any records subject to this part to the registrant in a format that the registrant's applications are capable of retrieving, displaying, and printing in a readable format.

(f) If a registrant changes application providers, the registrant must ensure that any records subject to this part are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.

(g) If a registrant transfers its electronic prescription files to another registrant, both registrants must ensure that the records are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.

(h) Digitally signed prescription records must be transferred or migrated with the digital signature.

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

Sec.

AUTHORITY: 21 U.S.C. 952, 953, 954, 957, 958.

SOURCE: 36 FR 7815, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

§ 1312.01 Scope of part 1312.

Procedures governing the importation, exportation, transshipment and intransit shipment of controlled substances pursuant to section 1002, 1003, and 1004 of the Act (21 U.S.C. 952, 953, and 954) are governed generally by those sections and specifically by the sections of this part.

§ 1312.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13969, Mar. 24, 1997]

IMPORTATION OF CONTROLLED SUBSTANCES

§ 1312.11 Requirement of authorization to import.

(a) No person shall import or cause to be imported any controlled substance listed in Schedule I or II or any narcotic controlled substance listed in Schedule III, IV or V or any non-narcotic controlled substance in Schedule III which the Administrator has specifically designated by regulation in § 1312.30 of this part or any non-narcotic controlled substance in Schedule IV or V which is also listed in Schedule I or II of the Convention on Psychotropic Substances unless and until such person is properly registered under the Act (or exempt from registration) and the Administrator has issued him a permit to do so pursuant to § 1312.13 of this part.

(b) No person shall import or cause to be imported any non-narcotic controlled substance listed in Schedule III, IV or V, excluding those described in paragraph (a) of this section, unless and until such person is properly registered under the Act (or exempt from registration) and has filed an import declaration to do so with the Administrator, pursuant to § 1312.18 of this part.

(c) When an import permit or declaration is required, a separate permit or declaration must be obtained for each consignment of controlled substances to be imported.

[36 FR 7815, Apr. 24, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 52 FR 17289, May 7, 1987]

§ 1312.12 Application for import permit.

(a) An application for a permit to import controlled substances shall be made on DEA Form 357. DEA Form 357 may be obtained from, and shall be filed with, the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Each application shall show the date of execution; the registration number of the importer; a detailed description of each controlled substance to be imported including the drug name, dosage form, National Drug Code (NDC) number, the Administration Controlled Substance Code Number as set forth in part 1308 of this chapter, the number and size of packages or containers, the name and quantity of the controlled substance contained in any finished dosage units, and the net quantity of any controlled substance (expressed in anhydrous

acid, base or alkaloid) given in kilograms or parts thereof. The application shall also include the following:

(1) The name, address, and business of the consignor, if known at the time application is submitted, but if unknown at that time, the fact should be indicated and the name and address afterwards furnished to the Administrator as soon as ascertained by the importer;

(2) The foreign port of exportation (*i.e.*, the place where the article will begin its journey of exportation to the United States);

(3) The port of entry into the United States;

(4) The latest date said shipment will leave said foreign port;

(5) The stock on hand of the controlled substance desired to be imported;

(6) The name of the importing carrier or vessel (if known, or if unknown it should be stated whether shipment will be made by express, freight, or otherwise, imports of controlled substances in Schedules I or II and narcotic drugs in Schedules III, IV, or V by mail being prohibited);

(7) The total tentative allotment to the importer of such controlled substance for the current calendar year;

(8) The total number of kilograms of said allotment for which permits have previously been issued and the total quantity of controlled substance actually imported during the current year to date.

(b) If desired, alternative foreign ports of exportation within the same country may be indicated upon the application (e.g., (1) Calcutta, (2) Bombay). If a formal permit is issued pursuant to such application, it will bear the names of the two ports in the order given in the application and will authorize shipment from either port. Alternate ports in different countries will not be authorized in the same permit.

[36 FR 7815, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 43218, Dec. 11, 1974; 45 FR 74715, Nov. 12, 1980; 51 FR 5319, 5320, Feb. 13, 1986; 52 FR 17289, May 7, 1987; 62 FR 13969, Mar. 24, 1997; 75 FR 10681, Mar. 9, 2010]

§ 1312.13 Issuance of import permit.

(a) The Administrator may authorize importation of any controlled substance listed in Schedule I or II or any narcotic drug listed in Schedule III, IV, or V if he finds:

(1) That the substance is crude opium, poppy straw, concentrate of poppy straw, or coca leaves, in such quantity as the Administrator finds necessary to provide for medical, scientific, or other legitimate purposes;

(2) That the substance is necessary to provide for medical and scientific needs or other legitimate needs of the United States during an emergency where domestic supplies of such substance or drug are found to be inadequate, or in any case in which the Administrator finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303 of the Controlled Substances Act (21 U.S.C. 823); or

(3) That the domestic supply of any controlled substance is inadequate for scientific studies, and that the importation of that substance for scientific purposes is only for delivery to officials of the United Nations, of the United States, or of any State, or to any person registered or exempted from registration under sections 1007 and 1008 of the Act (21 U.S.C. 957 and 958).

(4) That the importation of the controlled substance is for ballistics or other analytical or scientific purposes, and that the importation of that substance is only for delivery to officials of the United Nations, of the United States, or of any State, or to any person registered or exempted from registration under sections 1007 and 1008 of the Act (21 U.S.C. 957 and 958).

(b) The Administrator may require that such non-narcotic controlled substances in Schedule III as he shall designate by regulation in §1312.30 of this part be imported only pursuant to the issuance of an import permit. The Administrator may authorize the importation of such substances if he finds that the substance is being imported for medical, scientific or other legitimate uses.

(c) If a non-narcotic substance listed in Schedule IV or V is also listed in Schedule I or II of the Convention on Psychotropic Substances, 1971, it shall be imported only pursuant to the issuance of an import permit. The Administrator may authorize the importation of such substances if it is found that the substance is being imported for medical, scientific or other legitimate uses.

(d) The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

(e) Each import permit shall be issued in sextuplet and serially numbered, with all six copies bearing the same serial number and being designated ''original'' (Copy 1), ''duplicate'' (Copy 2), etc., respectively. All copies of import permits shall bear the signature of the Director or his delegate, and facsimiles of signatures shall not be used. No permit shall be altered or changed by any person after being signed by the Administrator or his delegate and any change or alteration upon the face of any permit after it shall have been signed by the Administrator or his delegate shall render it void and of no effect. Permits are not transferable. Each copy of the permit shall have printed or stamped thereon the disposition to be made thereof. Each permit shall be dated and shall certify that the importer named therein is thereby permitted as a registrant under the Act, to import, through the port named, one shipment of not to exceed the specified quantity of the named controlled substances, shipment to be made before a specified date. Not more than one shipment shall be made on a single import permit. The permit shall state that the Administrator is satisfied that the consignment proposed to be imported is required for legitimate purposes.

(f) Notwithstanding paragraphs (a)(1) and (a)(2) of this section, the Administrator shall permit, pursuant to section 1002(a)(1) or 1002(a)(2)(A) of the Act (21 U.S.C. 952(a)(1) or (a)(2)(A)), the importation of approved narcotic raw material (opium, poppy straw and concentrate of poppy straw) having as its source:

(1) Turkey,
(2) India,
(3) Spain,
(4) France,
(5) Poland,
(6) Hungary, and
(7) Australia.

(g) At least eighty (80) percent of the narcotic raw material imported into the United States shall have as its original source Turkey and India. Except under conditions of insufficient supplies of narcotic raw materials, not more than twenty (20) percent of the narcotic raw material imported into the United States annually shall have as its source Spain, France, Poland, Hungary and Australia.

[36 FR 23624, Dec. 11, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 41776, Aug. 18, 1981; 52 FR 17289, May 7, 1987; 73 FR 6851, Feb. 6, 2008]

§ 1312.14 Distribution of copies of import permit.

Copies of the import permit shall be distributed and serve purposes as follows:

(a) The original and quintuplet copies (Copy 1 and Copy 5) shall be transmitted by the Administration to the importer, who shall retain the quintuplet copy (Copy 5) on file as his record of authority for the importation, and shall transmit the original copy (Copy 1) to the foreign exporter. The foreign exporter will submit the original copy (Copy 1) to the proper governmental authority in the exporting country, if required, as a prerequisite to the issuance of an export authorization. This copy of the permit will accompany the shipment. Upon arrival of the imported merchandise, the District Director of the U.S. Customs Service at the port of entry will, after appraising the merchandise, forward the original copy (Copy 1) to the Drug Operations Section with a report on

the reverse side of such copy, showing the name of the port of importation, date prepared, name and net quantity of each substance, and report of analysis of the merchandise entered.

(b) The duplicate copy (Copy 2) shall be forwarded by the Administration to the proper governmental authorities of the exporting country.

(c) The quadruplet copy (Copy 4) shall be forwarded by the Administration to the District Director of the U.S. Customs Service at the U.S. port of entry, which shall be the customs port of destination in the case of shipments transported under immediate transportation entries, in order that the District Director may compare it with the original copy (Copy 1) and the bill of lading upon arrival of the merchandise. If a discrepancy is noted between corresponding items upon different copies of a permit bearing the same serial number when compared by the District Director, he shall refuse to permit entry of the merchandise until the facts are communicated to the Administration and further instructions are received.

(d) The triplicate copy (Copy 3) and sextuplet copy (Copy 6) shall be retained by the Administration.

[36 FR 7815, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and further amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 53 FR 48244, Nov. 30, 1988; 62 FR 13969, Mar. 24, 1997]

§ 1312.15 Shipments in greater or less amount than authorized.

(a) If the shipment made under an import permit is greater than the maximum amount authorized to be imported under the permit, as determined at the weighing by the District Director of the U.S. Customs Service, such difference shall be seized subject to forfeiture, pending an explanation; except that shipments of substances exceeding the maximum authorized amount by less than 1 percent may be released to the importer upon the filing by him of an amended import permit. If the substance is included in Schedule I, it will be summarily forfeited to the Government.

(b) If the shipment made under the permit is less than the maximum amount authorized to be imported under the permit as determined at the weighing by the District Director of the U.S. Customs Service, such difference, when ascertained by the Administration, shall be recredited to the tentative allotment against which the quantity covered by the permit was charged, and the balance of any such tentative allotment with any such recredits will remain available to the importer to whom made (unless previously revoked in whole or in part), for importations pursuant to any permit or permits as are requested and issued during the remainder of the calendar year to which the allotment is applicable. No permit shall be issued for importation of a quantity of controlled substances as a charge against the tentative allotment for a given calendar year, after the close of such calendar year, unless the Director of the Administration decides to make an exception for good cause shown.

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981]

§ 1312.16 Cancellation of permit; expiration date.

(a) A permit may be canceled after being issued, at the request of the importer, provided no shipment has been made thereunder. In the event that a permit is lost, the Administrator may, upon the production by the importer of satisfactory proof, by affidavit or otherwise, issue a duplicate permit. Nothing in this part shall affect the right, hereby reserved by the Administrator, to cancel a permit at any time for proper cause.

(b) An import permit shall not be valid after the date specified therein, and in no event shall the date be subsequent to 6 months after the date the permit is issued. Any unused import permit shall be returned for cancellation by the registrant to the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this

chapter for the current mailing address.

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 53 FR 48244, Nov. 30, 1988; 62 FR 13969, Mar. 24, 1997; 75 FR 10682, Mar. 9, 2010]

§ 1312.17 Special report from importers.

Whenever requested by the Administrator, importers shall render to him not later than 30 days after receipt of the request therefor a statement under oath of the stocks of controlled substances on hand as of the date specified by the Administrator in his request, and, if desired by the Administrator, an estimate of the probable requirements for legitimate uses of the importer for any subsequent period that may be designated by the Administrator. In lieu of any special statement that may be considered necessary, the Administrator may accept the figures given upon the reports subsequent by said importer under part 1304 of this chapter.

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13969, Mar. 24, 1997]

§ 1312.18 Contents of import declaration.

(a) Any non-narcotic controlled substance listed in Schedule III, IV, or V, not subject to the requirement of an import permit pursuant to § 1312.13 (b) or (c) of this chapter, may be imported if that substance is needed for medical, scientific or other legitimate uses in the United States, and will be imported pursuant to a controlled substances import declaration.

(b) Any person registered or authorized to import and desiring to import any non-narcotic controlled substance in Schedules III, IV, or V which is not subject to the requirement of an import permit as described in paragraph (a) of this section, must furnish a controlled substances import declaration on DEA Form 236 to the Import/Export Unit, Drug Enforcement Administration, not later than 15 calendar days prior to the proposed date of importation and distribute four copies of same as hereinafter directed in § 1312.19. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(c) DEA Form 236 must be executed in quintuplicate and will include the following information:

(1) The name, address, and registration number of the importer; and the name and address and registration number of the import broker, if any; and

(2) A complete description of the controlled substances to be imported, including drug name, dosage form, National Drug Code (NDC) number, the Administration Controlled Substances Code Number as set forth in part 1308 of this chapter, the number and size of packages or containers, the name and quantity of the controlled substance contained in any finished dosage units, and the net quantity of any controlled substance (expressed in anhydrous acid, base, or alkaloid) given in kilograms or parts thereof; and

(3) The proposed import date, the foreign port of exportation to the United States, the port of entry, and the name, address, and registration number of the recipient in the United States; and

(4) The name and address of the consignor in the foreign country of exportation, and any registration or license numbers if the consignor is required to have such numbers either by the country of exportation or under U.S. law.

(d) Notwithstanding the time limitations included in paragraph (b) of this section, an applicant may obtain a special waiver of these time limitations in emergency or unusual instances, provided that a specific confirmation is received from the Administrator or his delegate advising the registrant to proceed pursuant to the special waiver.

[36 FR 7815, Apr. 24, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 52 FR 17290, May 7, 1987; 62 FR 13969, Mar. 24, 1997; 75 FR 10682, Mar. 9, 2010; 77 FR 4237, Jan. 27, 2012]

§ 1312.19 Distribution of import declaration.

The required five copies of the controlled substances import declaration will be distributed as follows:

(a) Copy 1, Copy 2, and Copy 3 shall be transmitted to the foreign shipper. The foreign shipper will submit Copy 1 to the proper governmental authority in the foreign country, if required as a prerequisite to export authorization. Copy 1 will then accompany the shipment to its destination, and shall be retained on file by the importer. Copy 2 shall be detached and retained by the appropriate customs official of the foreign country. Copy 3 shall be removed by the District Director of the U.S. Customs Service at the port of entry, who shall sign and date the certification of customs on Copy 3, noting any changes from the entries made by the importer, and shall then forward that copy to the Drug Operations Section of the Administration.

(b) Copy 4 shall be forwarded, within the time limit required in §1312.18, directly to the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(c) Copy 5 shall be retained by the importer on file as his record of authority for the importation.

[36 FR 7815, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971; 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and further amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 53 FR 48244, Nov. 30, 1988; 62 FR 13969, Mar. 24, 1997; 75 FR 10682, Mar. 9, 2010]

EXPORTATION OF CONTROLLED SUBSTANCES

§1312.21 Requirement of authorization to export.

(a) No person shall in any manner export or cause to be exported from the United States any controlled substance listed in Schedule I or II, or any narcotic substance listed in Schedule III or IV, or any non-narcotic substance in Schedule III which the Administrator has specifically designated by regulation in §1312.30 of this part or any non-narcotic substance in Schedule IV or V which is also listed in Schedule I or II of the Convention on Psychotropic Substances unless and until such person is properly registered under the Act (or exempted from registration) and the Administrator has issued a permit pursuant to §1312.23 of this part.

(b) No person shall in any manner export or cause to be exported from the United States any non-narcotic controlled substance listed in Schedule III, IV, or V, excluding those described in paragraph (a) of this section, or any narcotic controlled substance listed in Schedule V, unless and until such person is properly registered under the Act (or exempted from registration) and has furnished a special controlled substance export invoice as provided by section 1003 of the Act (21 U.S.C. 953(e)) to the Administrator pursuant to §1312.28 of this part.

(c) A separate authorization request is obtained for each consignment of such controlled substances to be exported.

[36 FR 7815, Apr. 24, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 52 FR 17290, May 7, 1987; 77 FR 4237, Jan. 27, 2012]

§1312.22 Application for export permit.

(a) An application for a permit to export controlled substances shall be made on DEA Form 161, and an application for a permit to reexport controlled substances shall be made on DEA Form 161R. Forms may be obtained from, and shall be filed with, the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. Each application shall show the exporter's name, address, and registration number; a detailed description of each controlled substance desired to be exported including the drug name, dosage form, National Drug Code (NDC) number (in accordance with Food and Drug Administration regulations), the Administration Controlled Substance Code Number as set forth in Part 1308 of this chapter, the number and size of packages or containers, the name and quantity of the controlled substance contained in any finished dosage units, and the quantity of any controlled substance (expressed in anhydrous acid, base, or alkaloid) given in kilograms or parts thereof. The application shall include the name, address, and business of the consignee, foreign port of entry, the port of exportation, the approximate date of exportation, the name of

the exporting carrier or vessel (if known, or if unknown it should be stated whether shipment will be made by express, freight, or otherwise, exports of controlled substances by mail being prohibited), the date and number, if any, of the supporting foreign import license or permit accompanying the application, and the authority by whom such foreign license or permit was issued. The application shall also contain an affidavit that the packages are labeled in conformance with obligations of the United States under international treaties, conventions, or protocols in effect on May 1, 1971. The affidavit shall further state that to the best of affiant's knowledge and belief, the controlled substances therein are to be applied exclusively to medical or scientific uses within the country to which exported, will not be reexported therefrom and that there is an actual need for the controlled substance for medical or scientific uses within such country, unless the application is submitted for reexport in accordance with paragraphs (c) and (d) of this section. In the case of exportation of crude cocaine, the affidavit may state that to the best of affiant's knowledge and belief, the controlled substances will be processed within the country to which exported, either for medical or scientific use within that country or for reexportation in accordance with the laws of that country to another for medical or scientific use within that country. The application shall be signed and dated by the exporter and shall contain the address from which the substances will be shipped for exportation.

(b) There shall also be submitted with the application any import license or permit (and a translation thereof if in a foreign language) or a certified copy of any such license or permit issued by competent authorities in the country of destination, or other documentary evidence deemed adequate by the Administrator, showing that the merchandise is consigned to an authorized permittee, that it is to be applied exclusively to medical or scientific use within the country of destination, that it will not be reexported from such country, and that there is an actual need for the controlled substance for medical or scientific use within such country. (In the case of exportation of bulk coca leaf alkaloid, the submitted evidence need only show the material outlined in paragraph (a) of this section for such exportations.)

(c) Notwithstanding paragraphs (a) and (b) of this section, the Administration may authorize any controlled substance listed in Schedule I or II, or any narcotic drug listed in Schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country, if each of the following conditions is met, in accordance with §1003(f) of the Act (21 U.S.C. 953(f)):

(1) Both the country to which the controlled substance is exported from the United States (referred to in this section as the ''first country'') and the country to which the controlled substance is exported from the first country (referred to in this section as the ''second country'') are parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971;

(2) The first country and the second country have each instituted and maintain, in conformity with such Conventions, a system of controls of imports of controlled substances which the Administration deems adequate;

(3) With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country;

(4) With respect to the second country, substantial evidence is furnished to the Administration by the applicant for the export permit that—

(i) The controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; and

(ii) The controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country;

(5) The controlled substance will not be exported from the second country;

(6) The person who exported the controlled substance from the United States has complied with paragraph (d) of this section and a permit to export the controlled substance from the United States has been issued by the Administration; and

(7) Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States must deliver to the Administration documentation certifying that such export from the first country has occurred. If the permit issued by the Administration authorized the reexport of a controlled substance from the first country to more than one second country, notification of each individual reexport shall be provided. This documentation shall be submitted on company letterhead, signed by a responsible company official, and shall include all of the following information:

(i) Name of second country;

(ii) Actual quantity shipped;

(iii) Actual date shipped; and

(iv) DEA export permit number for the original export.

(d) Where a person is seeking to export a controlled substance for reexport in accordance with paragraph (c) of this section, the following requirements shall apply in addition to (and not in lieu of) the requirements of paragraphs (a) and (b) of this section:

(1) Bulk substances will not be reexported in the same form as exported from the United States, *i.e.*, the material must undergo further manufacturing process. This further manufactured material may only be reexported to a second country.

(2) Finished dosage units, if reexported, must be in a commercial package, properly sealed and labeled for legitimate medical use in the second country.

(3) Any proposed reexportation must be made known to the Administration at the time the initial DEA Form 161R is submitted. In addition, the following information must also be provided where indicated on the form:

(i) Whether the drug or preparation will be reexported in bulk or finished dosage units;

(ii) The product name, dosage strength, commercial package size, and quantity;

(iii) The name of consignee, complete address, and expected shipment date, as well as the name and address of the ultimate consignee in the second country.

(4) The application (DEA Form 161R) must also contain an affidavit that the consignee in the second country is authorized under the laws and regulations of the second country to receive the controlled substances. The affidavit must also contain the following statement, in addition to the statements required under paragraph (a) of this section:

(i) That the packages are labeled in conformance with the obligations of the United States under the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic Substances, 1971, and any amendments to such treaties;

(ii) That the controlled substances are to be applied exclusively to medical or scientific uses within the second country;

(iii) That the controlled substances will not be further reexported from the second country, and

(iv) That there is an actual need for the controlled substances for medical or scientific uses within the second country.

(5) If the applicant proposes that the shipment of controlled substances will be separated into parts after it arrives in the first country and then reexported to more than one second country, the applicant shall so indicate on the DEA Form 161R, providing all the information required in this section for each second country.

(6) Within 30 days after the controlled substance is exported from the United States, the person who exported the controlled substance shall deliver to the Administration documentation on the DEA Form 161R initially completed for the transaction certifying that such export occurred. This documentation shall be signed by a responsible company official and shall include all of the following information:

(i) Actual quantity shipped;

(ii) Actual date shipped; and

(iii) DEA export permit number.

(7) The controlled substance will be reexported from the first country to the second country (or second countries) no later than 180 days after the controlled substance was exported from the United States.

(8) Shipments that have been exported from the United States and are refused by the consignee in either the first or second country, or are otherwise unacceptable or undeliverable, may be returned to the registered exporter in the United States upon authorization of the Administration. In these circumstances, the exporter in the United States shall file a written request for the return of the controlled substances to the United States with a brief summary of the facts that warrant the return, along with a completed DEA Form 357, Application for Import Permit, with the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. The Administration will evaluate the request after considering all the facts as well as the exporter's registration status with the Administration. If the exporter provides sufficient documentation, the Administration will issue an import permit for the return of these drugs, and the exporter can then obtain an export permit from the country of original importation. The substance may be returned to the United States only after affirmative authorization is issued in writing by the Administration.

(e) In considering whether to grant an application for a permit under paragraphs (c) and (d) of this section, the Administration shall consider whether the applicant has previously obtained such a permit and, if so, whether the applicant complied fully with the requirements of this section with respect to that previous permit.

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 52 FR 17290, May 7, 1987; 62 FR 13969, Mar. 24, 1997; 72 FR 72927, Dec. 26, 2007; 75 FR 10682, Mar. 9, 2010]

§ 1312.23 Issuance of export permit.

(a) The Administrator may authorize exportation of any controlled substance listed in Schedule I or II or any narcotic controlled substance listed in Schedule III or IV if he finds that such exportation is permitted by subsections 1003(a), (b), (c), (d), or (f) of the Act (21 U.S.C. 953(a), (b), (c), (d), or (f).

(b) The Administrator may require that such non-narcotic controlled substances in Schedule III as shall be designated by regulation in §1312.30 of this part be exported only pursuant to the issuance of an export permit. The Administrator may authorize the exportation of such substances if he finds that such exportation is permitted by section 1003(e) of the Act (21 U.S.C. 953(e)).

(c) If a non-narcotic substance listed in Schedule IV or V is also listed in Schedule I or II of the Convention on Psychotropic Substances, it shall be exported only pursuant to the issuance of an export permit. The Administrator may authorize the exportation of such substances if he finds that such exportation is permitted by section 1003(e) of the Act (21 U.S.C. 953(e)).

(d) The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

(e) Each export permit shall be issued in septuplet and serially numbered, with all seven copies bearing the same serial number and being designated ''original'' (Copy 1), ''duplicate'' (Copy 2), etc., respectively. Each export permit shall be predicated upon an import certificate or other documentary evidence. Export permits are not transferable.

(f) No export permit shall be issued for the exportation, or reexportation, of any controlled substance to any country when the Administration has information to show that the estimates or assessments submitted with respect to that country for the current period, under the Single Convention on Narcotic Drugs, 1961, or the Convention on

Psychotropic Substances, 1971, have been, or, considering the quantity proposed to be imported, will be exceeded. If it shall appear through subsequent advice received from the International Narcotics Control Board of the United Nations that the estimates or assessments of the country of destination have been adjusted to permit further importation of the controlled substance, an export permit may then be issued if otherwise permissible.

[36 FR 23625, Dec. 11, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 52 FR 17290, May 7, 1987; 72 FR 72929, Dec. 26, 2007]

§ 1312.24 Distribution of copies of export permit.

Copies of the export permit shall be distributed and serve purposes as follows:

(a) The original, duplicate, and triplicate copies (Copy 1, Copy 2, and Copy 3) shall be transmitted by the Administration to the exporter who will retain the triplicate copy (Copy 3) as his record of authority for the exportation. The exporter shall present to the District Director of the U.S. Customs Service at the port of export and at the time of shipment, the original and duplicate copies (Copy 1 and Copy 2). After endorsing the port of export on the reverse side of the original and duplicate copies (Copy 1 and Copy 2) the District Director shall forward the endorsed original copy (Copy 1) with the shipment, and return the endorsed duplicate copy (Copy 2) to the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(b) The quadruplet copy (Copy 4) shall be forwarded by the Administrator to the District Director of the U.S. Customs Service at the port of export for comparison with the original copy (Copy 1) and for retention for the customs record.

(c) The quintuplet copy (Copy 5) shall be forwarded by the Administration to the officer in the country of destination who issued the import certificate, or other documentary evidence upon which the export permit is founded.

(d) The sextuplet and septuplet copies (Copy 6 and Copy 7) shall be retained by the Administration.

[36 FR 7815, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 53 FR 48244, Nov. 30, 1988; 62 FR 13969, Mar. 24, 1997; 75 FR 10682, Mar. 9, 2010]

§ 1312.25 Expiration date.

An export permit shall not be valid after the date specified therein, which date shall conform to the expiration date specified in the supporting import certificate or other documentary evidence upon which the export permit is founded, but in no event shall the date be subsequent to 6 months after the date the permit is issued. Any unused export permit shall be returned by the permittee to the Import/Export Unit for cancellation.

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 53 FR 48244, Nov. 30, 1988; 62 FR 13969, Mar. 24, 1997; 77 FR 4237, Jan. 27, 2012]

§ 1312.26 Records required of exporter.

The exporter shall keep a record of any serial numbers that might appear on packages of narcotic drugs in quantities of one ounce or more in such a manner as will identify the foreign consignee, along with Copy 3 of the export permit.

§ 1312.27 Contents of special controlled substances invoice.

(a) A person registered or authorized to export any non-narcotic controlled substance listed in Schedule III, IV, or V, which is not subject to the requirement of an export permit pursuant to §1312.23 (b) or (c), or any person registered or authorized to export any controlled substance in Schedule V, must furnish a special controlled substances export invoice on DEA Form 236 to the Import/Export Unit, Drug Enforcement Administration, not less than 15 calendar days prior to the proposed date of exportation, and distribute four copies of same as hereinafter directed in §1312.28 of this part. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(b) This invoice must be executed by the exporter in quintuplicate and include the following information.

(1) The name, address, and registration number, if any, of the exporter; and the name, address and registration number of the exporter broker, if any; and

(2) A complete description of the controlled substances to be exported including the drug name, dosage form, National Drug Code (NDC) number, the Administration Controlled Substances Code Number as set forth in part 1308 of this chapter, the number and size of packages or containers, the name and quantity of the controlled substance contained in finished dosage units, and the net quantity of any controlled substance (expressed in anhydrous acid, base, or alkaloid) given in kilograms or parts thereof; and

(3) The proposed export date, the port of exportation, the foreign port of entry, the carriers and shippers involved, method of shipment, the name of the vessel if applicable, and the name, address, and registration number, if any, of any forwarding agent utilized; and

(4) The name and address of the consignee in the country of destination, and any registration or license number if the consignee is required to have such numbers either by the country of destination or under United States law. In addition, documentation must be provided to show that:

(i) The consignee is authorized under the laws and regulations of the country of destination to receive the controlled substances, and that

(ii) The substance is being imported for consumption within the importing country to satisfy medical, scientific or other legitimate purposes, and that

(5) The reexport of non-narcotic controlled substances in Schedules III and IV, and controlled substances in Schedule V is not permitted under the authority of 21 U.S.C. 953(e), except as provided below:

(i) Bulk substances will not be reexported in the same form as exported from the United States, i.e, the material must undergo further manufacturing process. This further manufactured material may only be reexported to a country of ultimate consumption.

(ii) Finished dosage units, if reexported, will be in a commercial package, properly sealed and labeled for legitimate medical use in the country of destination.

(iii) Any reexportation be made known to DEA at the time the initial DEA Form 236, Controlled Substances Import/Export Declaration is completed, by checking the box marked ''other'' on the certification. The following information will be furnished in the remarks section:

(A) Indicate ''for reexport''.

(B) Indicate if reexport is bulk or finished dosage units.

(C) Indicate product name, dosage strength, commercial package size, and quantity.

(D) Indicate name of consignee, complete address, and expected shipment date, as well as, the name and address of the ultimate consignee in the country to where the substances will be reexported.

(E) A statement that the consignee in the country of ultimate destination is authorized under the laws and regulations of the country of ultimate destination to receive the controlled substances.

(iv) Shipments which have been exported from the United States and are refused by the consignee in the country of destination, or are otherwise unacceptable or undeliverable, may be returned to the registered exporter in the United States upon authorization of the Drug Enforcement Administration. In this circumstance, the exporter in the United States shall file a written request for reexport, along with a completed DEA Form 236, Import Declaration with the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. A brief summary of the facts that warrant the return of the substance to the United States along with an authorization from the country of export will be included with the request. DEA will evaluate the request after considering all the facts as well as the exporter's registration status with DEA. The substance may be returned to the United States only after affirmative authorization is issued in writing by DEA.

(c) Notwithstanding the time limitations included in paragraph (a) of this section, a registrant may obtain a special waiver of these time limitations in emergency or unusual instances; provided that a specific confirmation is received from the Administrator or his delegate advising the registrant to proceed pursuant to the special waiver.

[36 FR 7815, Apr. 24, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 52 FR 17290, May 7, 1987; 62 FR 13969, Mar. 24, 1997; 75 FR 10683, Mar. 9, 2010]

§ 1312.28 Distribution of special controlled substances invoice.

The required five copies of the special controlled substances export invoice, DEA (or BND) Form 236, will be distributed as follows:

(a) Copy 1 shall accompany the shipment and remain with the shipment to its destination.

(b) Copy 2 shall accompany the shipment and will be detached and retained by appropriate customs officials at the foreign country of destination.

(c) Copy 3 shall accompany the shipment and will be detached by the District Director of the U.S. Customs Service at the port of exportation, who shall sign and date the certification of customs on such Copy 3, noting any changes from the entries made by the exporter, and shall then promptly forward Copy 3 to the Import/Export Unit of the Administration.

(d) Copy 4 shall be forwarded, within the time limit required in §1312.27 of this part, directly to the Import/Export Unit, Drug Enforcement Administration. The documentation required by §1312.27(b)(4) of this part must be attached to this copy. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(e) Copy 5 shall be retained by the exporter on file as his record of authority for the exportation.

[36 FR 7815, Apr. 24, 1971, as amended at 36 FR 13387, July 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 52 FR 17291, May 7, 1987; 53 FR 48244, Nov. 30, 1988; 62 FR 13969, Mar. 24, 1997; 75 FR 10683, Mar. 9, 2010; 77 FR 4237, Jan. 27, 2012]

§ 1312.29 Domestic release prohibited.

An exporter or a forwarding agent acting for an exporter must either deliver the controlled substances to the port or border, or deliver the controlled substances to a bonded carrier approved by the consignor for delivery to the port or border, and may not, under any other circumstances, release a shipment of controlled substances to anyone, including the foreign consignee or his agent, within the United States.

§ 1312.30 Schedule III, IV, and V nonnarcotic controlled substances requiring an import and export permit.

The following Schedule III, IV, and V non-narcotic controlled substances have been specifically designated by the Administrator of the Drug Enforcement Administration as requiring import and export permits pursuant to sections 1002(b)(2) and 1003(e)(3) of the Act (21 U.S.C. 952(b)(2) and 953(e)(3)):

(a) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product.

(b) [Reserved]

[52 FR 17291, May 7, 1987, as amended at 64 FR 35930, July 2, 1999]

TRANSSHIPMENT AND IN-TRANSIT SHIPMENT OF CONTROLLED SUBSTANCES

§ 1312.31 Schedule I: Application for prior written approval.

(a) A controlled substance listed in schedule I may be imported into the United States for transshipment, or may be transferred or transshipped within the United States for immediate exportation, provided that:

(1) The controlled substance is necessary for scientific, medical, or other legitimate purposes in the country of destination, and

(2) A transshipment permit has been issued by the Administrator.

(b) An application for a transshipment permit must be submitted to the Import/Export Unit, Drug Enforcement Administration, at least 30 days, or in the case of an emergency as soon as practicable, prior to the expected

date of importation, transfer or transshipment. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. Each application shall contain the following:

(1) The date of execution;

(2) The identification and description of the controlled substance;

(3) The net quantity thereof;

(4) The number and size of the controlled substance containers;

(5) The name, address, and business of the foreign exporter;

(6) The foreign port of exportation;

(7) The approximate date of exportation;

(8) The identification of the exporting carrier;

(9) The name, address and business of the importer, transferor, or transshipper;

(10) The registration number, if any, of the importer, transferor or transshipper;

(11) The U.S. port of entry;

(12) The approximate date of entry;

(13) The name, address and business of the consignee at the foreign port of entry;

(14) The shipping route from the U.S. port of exportation to the foreign port of entry;

(15) The approximate date of receipt by the consignee at the foreign port of entry; and

(16) The signature of the importer, transferor or transshipper, or his agent accompanied by the agent's title.

(c) An application shall be accompanied by an export license, permit, or a certified copy of the export license, permit, or other authorization, issued by a competent authority of the country of origin (or other documentary evidence deemed adequate by the Administrator).

(d) An application shall be accompanied by an import license or permit or a certified copy of such license or permit issued by a competent authority of the country of destination (or other documentary evidence deemed adequate by the Administrator), indicating that the controlled substance:

(1) Is to be applied exclusively to scientific, medical or other legitimate uses within the country of destination;

(2) Will not be exported from such country; and

(3) Is needed therein because there is an actual shortage thereof and a demand therefor for scientific, medical or other legitimate uses within such country.

(e) Verification by an American consular officer of the signatures on a foreign import license or permit shall be required, if such license or permit does not bear the seal of the authority signing them.

(f) The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

(g) The Administrator shall, within 21 days from the date of receipt of the application, either grant or deny the application. The applicant shall be accorded an opportunity to amend the application, with the Administrator either granting or denying the amended application within 7 days of its receipt. If the Administrator does not grant or deny the application within 21 days of its receipt, or in the case of an amended application, within 7 days of its receipt, the application shall be deemed approved and the applicant may proceed.

[36 FR 7815, Apr. 24, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973, and further amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 53 FR 48244, Nov. 30, 1988; 62 FR 13969, Mar. 24, 1997; 75 FR 10683, Mar. 9, 2010]

§ 1312.32 Schedules II, III, IV: Advance notice.

(a) A controlled substance listed in Schedules II, III, or IV may be imported into the United States for transshipment, or may be transferred or transshipped within the United States for immediate exportation, provided that written notice is submitted to the Import/Export Unit, Drug Enforcement Administration, at least 15 days prior to the expected date of importation,

transfer or transshipment. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(b) Each advance notice shall contain those items required by §1312.31 (b) and (c).

[36 FR 7815, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 45 FR 74715, Nov. 12, 1980; 51 FR 5319, Feb. 13, 1986; 53 FR 48244, Nov. 30, 1988; 62 FR 13969, Mar. 24, 1997; 75 FR 10683, Mar. 9, 2010]

HEARINGS

§1312.41 Hearings generally.

(a) In any case where the Administrator shall hold a hearing regarding the denial of an application for an import, export or transshipment permit, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by sections 1002 and 1003 of the Act (21 U.S.C. 952 and 953), by §§1312.42–1312.47, and by the procedures for administrative hearings under the Act set forth in §§1316.41–1316.67 of this chapter.

(b) [Reserved]

[36 FR 23625, Dec. 11, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§1312.42 Purpose of hearing.

(a) If requested by a person applying for an import, export, or transshipment permit, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the issuance or denial of such permit to such person.

(b) Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

[36 FR 23625, Dec. 11, 1971, as amended at 37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§1312.43 Waiver or modification of rules.

The Administrator of the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

[36 FR 23625, Dec. 11, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

§1312.44 Request for hearing or appearance; waiver.

(a) Any applicant entitled to a hearing pursuant to §1312.42 and who desires a hearing on the denial of his application for an import, export, or transshipment permit shall, within 30 days after the date of receipt of the denial of his application, file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter.

(b) Any applicant entitled to a hearing pursuant to §1312.42 may, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(c) If any applicant entitled to a hearing pursuant to §1312.42 fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing unless he shows good cause for such failure.

(d) If the applicant waives or is deemed to have waived this opportunity for the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to §1312.47 without a hearing.

[37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§1312.45 Burden of proof.

At any hearing on the denial of an application for an import, export, or transshipment permit, the Administrator shall have the burden of proving that the requirements for such permit pursuant to sections 1002, 1003, and 1004

of the Act (21 U.S.C. 952, 953, and 954) are not satisfied.

[37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1312.46 Time and place of hearing.

(a) If any applicant for an import, export, or transshipment permit requests a hearing on the issuance or denial of his application, the Administrator shall hold such hearing. Notice of the hearing shall be given to the applicant of the time and place at least 30 days prior to the hearing, unless the applicant waives such notice and requests the hearing be held at an earlier time, in which case the Administrator shall fix a date for such hearing as early as reasonably possible.

(b) The hearing will commence at the place and time designated in the notice given pursuant to paragraph (a) of this section but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

[37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1312.47 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order on the issuance or denial of the application for and import, export, or transshipment permit. The order shall include the findings of fact and conclusions of law upon which the order is based. The Administrator shall serve one copy of his order upon the applicant.

[37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

PART 1313—IMPORTATION AND EXPORTATION OF LIST I AND LIST II CHEMICALS

Sec.

AUTHORITY: 21 U.S.C. 802, 830, 871(b), 971.

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

§ 1313.01 Scope.

Procedures governing the importation, exportation, transshipment and in-transit shipment of listed chemicals pursuant to section 1018 of the Act (21 U.S.C. 971) are governed generally by that section and specifically by the sections of this part.

[54 FR 31665, Aug. 1, 1989, as amended at 60 FR 32465, June 22, 1995]